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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
STRZELECKA, TERESA E	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 10/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/010,742	DILLON ET AL.	
	Examiner	Art Unit	
	Teresa E Strzelecka	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,8 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,8 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3,10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I (claims 1, 3, 4, 8, and 15, drawn to SEQ ID NO: 305) in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 2, 5-7, 9-14 and 16-21 were cancelled by Applicants. Claims 1, 3, 4, 8 and 15 are pending and will be examined.

Priority

3. Claims 1, 3, 4, 8 and 15, as amended, are entitled to the priority date of the parent application No. 09/910,689, since this is an application in which the SEQ ID NO: 305 was first introduced.

Oath/Declaration

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> It does not identify the mailing address of each inventor. A mailing address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing address should include the ZIP Code designation. The mailing address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

5. ?? The declaration does not contain a reference to priority applications.

Information Disclosure Statement

6. The information disclosure statements (IDS) submitted on January 31, 2002 and June 20, 2003 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 101, utility

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

8. Claims 1, 3, 4, 8 and 15 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

The claimed subject matter is not supported by a specific, substantial, and credible utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter.

Polynucleotide with SEQ ID NO: 305 is the cDNA sequence of the open reading frame of a splice variant of B854P referred to as 228686_8 (page 16, lines 3,4). On page 104, Applicants explain that the 228686_8 sequence was recovered from LifeSeq Gold™ database by comparing the database with a polynucleotide with SEQ ID NO: 52 (B854P), which may represent a potential splice form of the B854P gene. The 228686_8 sequence encodes a putative protein with SEQ ID NO: 307, the cDNA of which has SEQ ID NO: 305. Applicants assert that the nucleic acid sequence denoted as 228686_8 is full-length and is 51% identical to rabbit P450 cytochrome sequences (page 104, lines 8-22). Applicants did not provide the sequence alignment or an indication to which cytochrome P450 the sequence was compared.

Sequence search performed at USPTO did not reveal any significant homology to P450 proteins of any origin. The following homologies were found (see copies of sequence alignments):

1) 99.9% identity to a polynucleotide with SEQ ID NO: 29 from a patent publication No. US 2003/0027988 A1. This polynucleotide is overexpressed in colon cancer cells, but no structural or functional information for the protein encoded by it was provided, and no specific or substantial utility was described for either the polynucleotide or the protein encoded by it.

2) 99.9% identity to SEQ ID NO: 55 of the patent publication No. US 2003/0022334 A1. Again, this publication does not contain any information about the function of a protein encoded by

SEQ ID NO: 55, and does not provide any specific or substantial utility was described for either the polynucleotide or the protein encoded by it.

3) 21.2% identity to a nucleic acid sequence with an accession number AI820775, which is human EST fragment, similar to rabbit cytochrome P450 4B1 (according to clone definition); no functional information provided.

4) 20.4% identity to a nucleic acid sequence with an accession number BI772715, which is human EST fragment; no function information provided.

Absent factual evidence, a percentage sequence similarity of less than 100 % is not deemed to reasonably support to one skilled in the art whether the biochemical activity of the claimed subject matter would be the same as that of such a similar known biomolecule. However, in all of the four cases above none of the similar polynucleotides has utility in view of the fact that the first two encode proteins with unknown function and undetermined utility, and the third and fourth ones are short polynucleotide fragments with unknown function.

The claimed polynucleotide (SEQ ID NO: 305) is not supported by a specific asserted utility because the disclosed uses of the polynucleotide are not specific and are generally applicable to a wide variety of polynucleotides. The specification states that the polynucleotides may be useful as hybridization probes, PCR primers (page 33, lines 9-22; page 39, lines 8-29; page 40; page 41, lines 1-18), for encoding of polypeptides cross-reactive with other polypeptides (page 33, lines 23-29), for sequence comparisons with other polynucleotides (page 34, lines 12-29; page 35), for mutagenesis to provide derivative polypeptides (page 36, lines 23-29; page 37, 38), for therapeutic purposes as antisense ologonucleotides (page 41, lines 19-29; page 42; page 43, lines 1-7), for design of ribozymes (page 43, lines 8-29; page 44, 45; page 46, lines 1-20), parts of expression vectors and for gene therapy and vaccines (page 72 lines 3-29; page 73). These are non-specific

uses that are applicable to nucleic acids in general and not particular or specific to the nucleic acid being claimed.

Further, the claimed polynucleotide compound is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the protein compound such that another non-asserted utility would be well established for the compounds.

Applicants state in lines 9 and 10 of page 16 that the compositions described in the specification could be used for the therapy and diagnosis of cancer, particularly breast cancer. However, in order for a polynucleotide (or a polypeptide) to be useful for diagnosis of a disease, there must be a well-established or disclosed correlation or relationship between the claimed polynucleotide (or a polypeptide) and a disease or disorder. The presence of a polynucleotide (or a polypeptide) in tissue that is derived from cancer cells (in this case from breast cancer cells) is not sufficient for establishing a utility in diagnosis of disease in the absence of some information regarding a correlative or causal relationship between the expression of the claimed cDNA and the disease. If a molecule is to be used as a surrogate for a disease state, some disease state must be identified in some way with the molecule. There must be some expression pattern that would allow the claimed polynucleotide (or a polypeptide) to be used in a diagnostic manner. Many proteins are expressed in normal tissues and diseased tissues. Therefore, one needs to know, e.g., that the

claimed polynucleotide (or a polypeptide) is either present only in cancer tissue to the exclusion of normal tissue or is expressed in higher levels in diseased tissue compared to normal tissue (i.e. overexpression). Evidence of a differential expression might serve as a basis for use of the claimed polynucleotide (or a polypeptide) as a diagnostic for a disease. However, in the absence of any disclosed relationship between the claimed polynucleotide or the protein that is encoded thereby and any disease or disorder and the lack of any correlation between the claimed polynucleotide or the encoded protein with any known disease or disorder, any information obtained from an expression profile would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner*, 148 USPQ at 696. The disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101.

Applicant should explicitly identify a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

Claim Rejections - 35 USC § 112, written description

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1, 3, 4, 8 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 (c) is drawn to an isolated polynucleotide comprising sequences consisting of at least 20 contiguous residues of the sequence provided in SEQ ID NO: 305, claim 1 (d) is drawn to an isolated polynucleotide comprising sequences that hybridize to the sequence provided in SEQ ID NO: 305, claims 1 (e) and (f) are directed to an isolated polynucleotide comprising a sequence having at least 75% [or 90%] sequence identity with the polynucleotide with SEQ ID NO: 305, and claim 1 (g)) is drawn to an isolated polynucleotide comprising degenerate variants of the sequence provided in SEQ ID NO: 305. The instant specification only describes the nucleic acid comprising SEQ ID NO: 305. However, Applicants have not adequately described a representative number of sequences consisting of at least 20 contiguous residues of the sequence provided in SEQ ID NO: 305, or sequences having 75 or 90% sequence identity with SEQ ID NO: 305, or hybridizing to SEQ ID NO: 305 or degenerate variants of SEQ ID NO: 305. In fact, only one sequence was provided, that of SEQ ID NO: 305.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

All of the current claims encompass a genus of nucleic acids which are different from those disclosed in the specification. The genus includes variants for which no written description is provided in the specification. This large genus is represented in the specification by only the particularly named SEQ ID NO: 305 with 1518 bp. Thus, applicant has express possession of only

one particular sequence, in a genus which comprises hundreds of millions of different possibilities. Here, no common element or attributes of the sequences are disclosed, not even the presence of certain domains. No structural limitations or requirements which provide guidance on the identification of sequences which meet these functional limitations is provided. Further, these claims encompass all possible 20mers (of which there are 1518-20+1= 1499 sequences), all possible polynucleotides and oligonucleotides which would hybridize to SEQ ID NO: 305 under moderately stringent conditions (of which there are possibly millions), all possible sequences with 75% and 90% sequence identity, and all possible degenerate variants, and only one specific nucleic acid sequence has been provided. No written description of alleles, of upstream or downstream regions containing additional sequence, or of alternative splice variants has been provided in the specification.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

> "A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. "

In the current situation, the definition of the polynucleotides from claims 1 (c)-(g) lack any specific structure, is precisely the situation of naming a type of material which is generally known to likely exist, but, except for the one specific sequence, is in the absence of knowledge of the material

composition and fails to provide descriptive support for the generic claim to "an isolated polynucleotide comprising sequences consisting of at least 20 contiguous residues of the sequence provided in SEQ ID NO: 305", for example.

In the instant application, certain specific SEQ ID NOs are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids other than those expressly disclosed which comprise SEQ ID NO: 305. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

Claim Rejections - 35 USC § 112, second paragraph

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claim 1 (b) is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1(b) is indefinite over the recitation of "complements of a sequence". Since there is only one full-length complement of a given sequence, it is not clear what is meant by a plurality of complements (for example, does it mean that complements which are not full-length are included?).

Claim interpretation

13. Before proceeding with the rejections, meaning of terms used in the claims is defined:

A) the term "complement" of a sequence is interpreted as a full-length complement, since no definition was provided by Applicants,

B) the term "degenerate variant of a sequence" is interpreted as any sequence which differs from the original, according to Applicants' definition: "Typically, polynucleotide variants will contain one or more substitutions, additions, deletions and/or insertions, preferably such that the immunogenicity of the polypeptide encoded by the variant polynucleotide is not substantially diminished relative to a polypeptide encoded by a polynucleotide sequence specifically set forth herein). The term "variants" should also be understood to encompasses homologous genes of xenogenic origin." (page 32, lines 22-27).

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. Claims 1, 3, 4, 8 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Glucksmann (US 2003/0022334 A1).

Regarding claim 1 (c), (e)-(f), Glucksmann teaches an isolated polynucleotide with SEQ ID NO: 3 (33312 polynucleotide), which is 99.9% identical to an isolated polynucleotide SEQ ID NO: 305 (see sequence alignment) (page 1, [0006]; page 11, [0121]). Therefore, Glucksmann teaches a sequence which consists of at least 20 contiguous residues of SEQ ID NO: 305 (claim 1 (c)), a sequence having at least 75% and 90% identity to SEQ ID NO: 305 (claim 1 (e) and (f)).

Regarding claim 1 (d), Glucksmann teaches nucleic acid molecules which hybridize under stringent conditions to SEQ ID NO: 3 (page 1, [007]), which means that they wouls also hybridize under moderately stringent conditions to SEQ ID NO: 305.

Regarding claim 1 (g), Glucksmann teaches variants of 3312 nucleic acid molecules, including degenerate variants (page 11, [0121]; page 13, [0146]).

Regarding claims 3 and 4, Glucksmann teaches an expression vector comprising 33312 nucleic acids and host cells containing the nucleic acids (page 1, [0008]).

Regarding claim 8, Glucksmann teaches nucleic acid fragments suitable as primers or hybridization probes for the detection of 33312 nucleic acids (page 1, [0009]; page 11, [0127], [0128]).

Regarding claim 15, Glucksmann teaches diagnostic kits for detection of 33312 nucleic acids, the kits comprising oligonucleotides (page 31, [0345], [0347]).

16. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

TS
October 9, 2003

TS

JEFFREY FREDMAN
PRIMARY EXAMINER